REMARKS

Claims 1-3, 5-8 and 16-18 were pending for purposes of the instant Office Action.

Claims 4 and 15 were previously canceled. Claims 9-14 and 19-20 were previously canceled without prejudice in response to a Restriction Requirement. Claim 1 is currently amended as shown above, without prejudice. Support for the amendments can be found, for example, on paragraphs [0006], [0007], [0024] to [0027] and [0133] to [0137] of U.S. Patent Publication No. 2006/0014223 of the present specification. As claim 4 was previously canceled, Claim 17 has been amended without prejudice to depend on pending claim 6. New claims 21 to 23 have been added for consideration. Support for new claims 21 to 23 may be found in the specification as filed, for example, as evidenced in paragraph [0006] of U.S. Patent Publication No. 2006/0014223 of the present specification. Applicants submit that no new matter has been added by virtue of this amendment.

Accordingly, claims 1-3, 5-8, 16-18 and 21 to 23 remain pending.

Summary of Telephonic Interview

Applicant noted that the Office Action Summary attached to the Office Action mailed on March 11, 2009 incorrectly indicated that the present Office Action was a Final Office Action. The undersigned contacted Examiner Minh Tam G. Davis on April 1, 2009 via telephone to ascertain the proper status of the present application. Examiner Davis confirmed to the undersigned that the pending Office Action was a Non-final Office Action and Examiner Davis also noted that a typographical error was made in the Office Action Summary mailed on March 11, 2009.

Enablement Rejections

Claims 1 to 3, 5 to 8, and 16 to 18 remain rejected under 35 U.S.C. § 112, first paragraph, allegedly for lack of enablement for a method for detecting hepatic cancer. The Office Action states that "it is noted that the test sample in the claimed method could be from any patients, and not necessarily patients suspected of having hepatic cancer. Further, it is not clear what constitutes "normal" blood, serum or plasma, which is not necessarily blood, serum

or plasma from non-cancerous control subjects." See Office Action, page 3, lines 14-17. In light of the Examiner's comments and to expedite prosecution of this application, claim 1 has been amended without prejudice to recite in relevant part: **"A method for identifying subjects suspected of having cancer**, said method comprising detecting a soluble GPC3 protein level in a **test sample obtained from a subject suspected of having cancer** selected from the group consisting of blood, serum and plasma, and **determining whether said detected soluble GPC3 level in the test sample obtained from a subject suspected of having cancer is greater than a control level of GPC3 in normal non-cancerous blood, serum or plasma." Emphasis added.** Therefore the claim is enabled because a person of ordinary skill in the art would be able to measure the GPC3 in the sample, and determine whether a test sample (blood, serum, or plasma) contains "greater levels" of GPC3 than the levels of GPC3 found in a normal control, and thereby be enabled to "identify" a subject/patient suspected of having cancer. The present invention is not limited to hepatic cancer, but is applicable to the identification of subjects/patient suspected of having other cancers (e.g . lung cancer, colon cancer, mammary cancer, prostate cancer, pancreatic cancer, and lymphomas), as evidenced in paragraph [0007] of U.S. Patent Publication No. 2006/0014223 of the present specification: "The expression of GPC3 protein has also been detected in cancer cell lines other than hepatic cancer cell lines, such as lung cancer, colon cancer, mammary cancer, prostate cancer, pancreatic cancer, and lymphomas. Hence, GPC3 may possibly be applied to the diagnosis of hepatic cancer as well as many other cancers." Thus, the present invention is not limited solely to hepatic cancer as suggested by the Examiner in the present Office Action.

Applicants reassert that there is no requirement that the skilled artisan use ONLY the claimed method as a final determination before treatment. Applicants respectfully submit that one of ordinary skill can determine whether a test sample (blood, serum, or plasma) contains "greater levels" of GPC3 than the levels of GPC3 found in a normal control, and thereby identify subjects suspected of having cancer, as disclosed in the subject application. Applicants maintain that such identification would not require undue experimentation.

In view of the foregoing, it is respectfully submitted that the subject claims are enabling, and reconsideration and withdrawal of the rejection under 35 USC 112, first paragraph, is respectfully requested.

Indefiniteness Rejections

Claims 1 to 3, 5 to 8, and 16 to 18 were also rejected under 35 U.S.C. § 112, second paragraph. Specifically, claims 1-3, 5-8, 16, and 18 were alleged to be indefinite "because it not clear in claim 1 how normal blood, serum or plasma "corresponds" to the test sample." See Office Action, page 4, lines 4-5. Independent claim 1 as been amended in relevant part to recite: "determining whether said detected soluble GPC3 level in the test sample obtained from a subject suspected of having cancer is greater than a control level of GPC3 in normal non-cancerous blood, serum or plasma." Applicants respectfully submit that amended claim 1 provides further clarification as to the greater levels of GPC3 in specific test samples, as compared to normal controls. The measured levels of GPC3 in blood, plasma or serum obtained from the test samples from a subject suspected of having cancer is compared to a corresponding normal non-cancerous blood, plasma, or serum level of GPC3, which is known in the art. Applicants respectfully submit that claim 1, as amended, clearly recites how normal blood, serum or plasma "corresponds" to the test sample.

Claims 2-3, 5-8, 16, and 18 depend either directly or indirectly from claim 1.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection to independent claim 1 and dependent claims 2-3, 5-8, 16, and 18 under 35 U.S.C. § 112, second paragraph.

Claim 17 was also rejected under 35 U.S.C. § 112, second paragraph for being indefinite "because it depends on cancelled claim 4." See Office Action, page 4, lines 6-7. Claim 17 has been amended without prejudice to depend on pending claim 6.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection to claim 17 under 35 U.S.C. § 112, second paragraph.

CONCLUSION

An early and favorable action on the merits is earnestly solicited. The Examiner is respectfully requested to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
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